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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,464	12/20/2001	Sheila J. Kelly	1416.07US01	1559
22865	7590	10/14/2004	EXAMINER	
ALTERA LAW GROUP, LLC 6500 CITY WEST PARKWAY SUITE 100 MINNEAPOLIS, MN 55344-7704			WITZ, JEAN C	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,464

Applicant(s)

KELLY ET AL.

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 29-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed July 1, 2004 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 6-9, 21, 27, 36, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Atala (U.S. Patent 6,368,859).

Applicants assert that Atala does not teach every element of the invention set forth in independent claims 1 and 36 and therefore fails to anticipate claims 1 and 36. Applicants particularly assert that Atala is directed to an artificial fascial sling for treating urinary incontinence and that Atala does not disclose "a first layer having at least about 5 dry weight percent flexibility modifying agent" or a "second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer." Further, Applicants assert that "Atala does not disclose at least one layer including a reconstituted composition" and points to the specification at page 16, lines 17-20 which

states that "Reconstituted compositions involve mixtures of synthetic or purified materials, possibly blended with fragmented natural materials, to form a non-natural material for incorporation into the composite. Thus the composites are distinguishable from native tissues that have layers."

Applicants' assertions are not persuasive. During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, ___ F.3d ___, 2004 WL 1067528 (Fed. Cir. May 13, 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.).

Claim 1 requires a composite matrix comprising a first layer having at least about 5 dry weight percent flexibility modifying agent and a second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer, wherein at least one layer comprises a reconstituted composition. Broadest reasonable interpretation of the claim defines the claim as composed of two layers, one of which has at least 5 dry

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weight percent less "flexibility modifying agent" than the other layer. Therefore, if one layer has no "flexibility modifying agent" and the other layer has at least 5 dry weight percent of "flexibility modifying agent", this limitation of the claim is met. Broadest reasonable interpretation of the term "flexibility modifying agent" is defined as a component of the matrix that "modifies" or "changes" the flexibility of the matrix. This is taken to mean the agent makes the matrix either more or less flexible, since the term "modifying" does not indicate the nature of the change. Applicants identify only elastin as an appropriate "flexibility modifying agent."

The patent to Atala discloses a biocompatible matrix for use as a fascial sling. The matrix has at least two layers. The first layer is a layer of collagen-secreting cells that produce collagen. The second layer is a layer of elastin-secreting cells that produce elastin. Since the first layer contains no elastin and the second layer contains sufficient elastin to provide elasticity to the matrix, it is deemed that this amount of elastin is inherently at least 5 dry weight percent of elastin more than is found in the layer containing the collagen-secreting cells. Since the collagen-secreting cells secrete collagen into that layer of the matrix, the amounts of collagen defined in claims 2-3, absent objective evidence to the contrary, are deemed inherent in the disclosure of the patent. The matrix also contains a biocompatible substrate, as listed at col. 4. Most of these materials are non-native to human tissues. Therefore, the patent is deemed to anticipate the cited claims as it inherently and expressly meets each and every limitation

Applicants, in the response, by pointing to specification at page 16, lines 17-20 (which states that "Reconstituted compositions involve mixtures of synthetic or purified

materials, possibly blended with fragmented natural materials, to form a non-natural material for incorporation into the composite. Thus the composites are distinguishable from native tissues that have layers.”), appear to be asserting that the term “reconstitution” must be limited to this definition. First, the composite matrices of Atala, while attempting to mimic native tissues, are clearly not identical to native tissues. Further, this argument is not persuasive as addressed above because during patent examination, the pending claims must be “given their broadest reasonable interpretation consistent with the specification” and are not read solely in light of or as limited by the specification. Per Webster’s dictionary, broadest reasonable interpretation of “reconstitute” includes “to reconstruct”. The matrices of Atala meet this limitation since they have been reconstructed from cells originally found in tissue.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-28 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bell et al, Delmotte, Gregory and Li et al. taken as as whole.

Applicants assert that the rejection was based upon improper hindsight reconstruction. In response to this argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant situation, all of the cited references teach reconstituted biopolymeric composite matrices having multiple layers having the components as claimed and in the amounts as claimed. The motivation lies in the evaluation of the references taken as a whole that suggests to one of ordinary skill in the art that multiple layered matrices are useful, and particularly as suggested by Atala, and specifically layers that contain different components for contributing different functions to the matrices.

For example, Li et al. teaches a double-layer oriented biopolymeric membrane where each layer is composed of reconstituted collagen. Per col. 3, other biopolymeric materials may be included, including elastin and glycosaminoglycans. The layers are crosslinked and can be glued together using a fibrin glue. The layers also meet the thickness limitations of the claims. Therefore, Li et al. differs from the claims by the explicit recitation of the difference of elastin present in each layer; however, the disclosure suggests that determination of the varying amounts of the components of each membrane is well within the skill of the practitioner as evidenced by the recitation at col. 10, that states that one skilled in the art is capable of making various changes and modifications dependent upon the various usages of the membrane. As a result, since Atala suggest that a collagen layer and an elastic layer is beneficial, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include more elastin in one layer than the other in order to provide both elasticity and strength to the membrane. The claims require only a 5% difference in elastin between the two layers, which is clearly met by the language of Atala.

Further, the biopolymer membranes of Delotte are similar to those claimed in that multiple layers are contemplated and each layer comprises biomaterials claimed, as disclosed on page 2 of the published application at paragraph [0014]. The membranes are crosslinked and may include living cells including those claimed and also may include growth factors such as claimed. The membrane may be crosslinked. Again, the document states that other specific forms are well within the skill of the practitioner. Again, in this case, the only difference between the disclosure and the claims is the

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explicit reference to a composite matrix where one layer differs in elastin content by at least 5% over another. Again, Atala shows that such composites have important uses.

Finally, Gregory teaches that elastin-based matrices are known to be used as graft materials. These matrices can be compressed to other matrices or each other by using heat or fibrin glues and may contain cells and/or drugs appropriate to the use and area to be treated with the matrix.

Therefore, it would have been obvious to produce a multi-layer reconstituted matrix with differing amounts of elastin in the layers as suggested that such layers have biological value when used as in vivo implants. The claims recite conventional matrix components (cells, growth factors, friction reducing macromolecules) and the layers of the matrices are attached to one another in conventional manners (crosslinking, fibrin glues and heat).

Applicants fail to address these aspects of the references and merely state that the claims are not obvious in view of the references. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

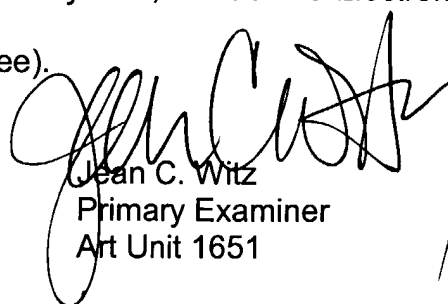
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz
Primary Examiner
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